**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

| | |
|---|---|
| ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., ABBOTT BIOTECHNOLOGY, LTD.<br><br>Plaintiffs,<br><br>v.<br><br>CENTOCOR ORTHO BIOTECH, INC., CENTOCOR BIOLOGICS, LLC.<br><br>Defendants. | **C.A. No. 4:09-CV-11340 (FDS)**<br><br>**JURY TRIAL DEMANDED** |
| CENTOCOR ORTHO BIOTECH, INC.<br><br>Plaintiff,<br><br>v.<br><br>ABBOTT GMBH & CO., KG,<br><br>Defendant. | **C.A. No. 4:10-CV-40003 (FDS)** |

**ABBOTT'S BRIEF IN SUPPORT OF ITS MOTION**
**FOR JUDGMENT AS A MATTER OF LAW**

## I. ABBOTT IS ENTITLED TO JMOL THAT ITS PATENTS ARE NOT INVALID

Plaintiffs Abbott GMBH & Co., KG, Abbott Bioresearch Center, Inc., and Abbott Biotechnology, Ltd. ("Abbott")[1] move for judgment as a matter of law ("JMOL") against Defendants Centocor Ortho Biotech, Inc., and Centocor Biologics, LLC ("Centocor") that all asserted claims of U.S. Patent Nos. 6,914,128 ("the '128 patent") and 7,504,485 ("the '485 patent") are not invalid. Abbott's asserted claims are claims 29, 30, 32, and 64 of the '128 Patent and claim 11 of the '485 Patent.

Judgment as a matter of law is appropriate if the presentation of the party's case reveals no "legally sufficient evidentiary basis" for a reasonable jury to find for that party. *Mag Jewelry Co., Inc. v. Cherokee, Inc.*, 496 F.3d 108, 117 (1st Cir. 2007); *see also* Fed. R. Civ. P. 50(a)(1). In addition, it is well-established that a patent is presumed valid, and the defendant has the burden to establish any invalidity defense by "clear and convincing" evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

At the close of its case, Centocor has failed to present any "legally sufficient evidentiary basis" for a reasonable jury to find that Abbott's asserted patent claims are invalid. In particular, Centocor has failed to present legally sufficient evidence to support its defenses that Abbott's asserted patent claims are invalid for lack of written description or enablement under 35 U.S.C. § 112, ¶ 1, for obviousness under 35 U.S.C. § 103, or for anticipation under 35 U.S.C. § 102. Accordingly, Abbott requests that the Court grant judgment as a matter of law that all of Abbott's asserted claims are not invalid.

[1] Effective June 25, 2012, Abbott Biotechnology, Ltd. changed its name to AbbVie Biotechnology Ltd. (D.I. 368.)

## II. CENTOCOR'S WRITTEN DESCRIPTION DEFENSE FAILS AS A MATTER OF LAW

A patent provides an adequate written description under 35 U.S.C. § 112, ¶ 1 when it "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The parties agree that the relevant test for determining compliance with the written description requirement is whether Abbott's asserted patents disclose:

> ***either*** [1] a representative number of species falling within the scope of the [claimed] genus ***or*** [2] structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.

*Id.* at 1351 (emphasis added) (quoting *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997)). Under this test, there are two ways that a patent can provide an adequate written description of a claimed genus. One is to provide a "representative number of species falling within the scope of the [claimed] genus." *Id.* The other is to provide the "structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* Only the first test ("representative species") is at issue in this case.

The Federal Circuit has explained that a "representative number of species" means that "the species which are adequately described are representative of ***the entire genus***." *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) (emphasis added). "Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus." *Id.* Critically, "applicants are not required to disclose every species encompassed by their claims even in an unpredictable art." *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997). Nor are claims limited to the embodiments disclosed in the specification. *Amgen Inc. v. Hoechst*

*Marion Roussel, Inc.*, 314 F.3d 1313, 1328 (Fed. Cir. 2003); *see also Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001) ("[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.").

Centocor's written description defense ignores this precedent by incorrectly collapsing the "representative species" test and the "structural features" test into one. Each of Centocor's alleged "differences" between the species disclosed in the patent and Stelara – the only known member of the genus that is not disclosed – are structural differences, e.g., the difference in amino acid sequence, or functional differences that are a consequence of a different structure. The representative species test, however, does not require that the species be structurally similar to the accused product or to every other species in the genus. If it did, it would be redundant of the "structural features" test. Instead, the representative species test requires only that a subset of the genus represent the "***variation*** within the genus." *Carnegie Mellon*, 541 F.3d at 1124. The antibodies disclosed in Abbott's patents represent dozens of antibodies having substantial variability in the complementarity determining region ("CDR") of the antibody – the critical region responsible for the functional characteristics of the claimed antibodies. *See* Trial Transcript, Day 5 at 41:18-24, 130:21-131:2 (Centocor's expert Dr. Donald Siegel testified that there are only "dozens" of antibodies in Abbott's claims).[2] This structural variability results in antibodies that have varying functional characteristics, including widely varying binding affinities to IL-12, a distinguishing feature of the claimed invention.

Rather than address the legal issue in the case, Centocor has offered evidence largely devoted to comparing a single embodiment of the patent (J695) to Stelara. Such a comparison

[2] *See also* Trial Transcript, Day 3 at 144:1-4 (Centocor's expert Dr. Eck testified that "those particular loops or regions are called the complementarity determining regions. They're the bits of antibody sequence that are responsible for most directly recognizing their target.")

would be irrelevant even in an infringement case. It proves nothing about the written description requirement. Because Centocor has not shown by clear and convincing evidence that the disclosed species are not representative of the claimed genus, judgment as a matter of law should enter against Centocor's written description defense.

## III. CENTOCOR'S ENABLEMENT DEFENSE FAILS AS A MATTER OF LAW

Judgment as a matter of law should also enter against Centocor's defense that the asserted patent claims are not enabled. Centocor's expert provided no evidence whatsoever on whether undue experimentation would be required to practice the claim, failing to address in detail even one of the factors recognized by the Federal Circuit as relevant to the issue. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (explaining factors for determining undue experimentation). Nor can Centocor dispute that a person of ordinary skill in the art would be able to make and use the representative antibodies disclosed in the patent that come within the scope of the asserted claims. *See In re Angstat*, 537 F.2d 498, 502-03 (C.C.P.A. 1976) (affirming the BPAI's conclusion that enablement of 40 representative species was adequate support for a genus claim). To the extent that Centocor is suggesting that Abbott was required to enable antibodies made by transgenic mice or using a $V_H5$ gene, it incorrectly implies that more than one method of making a claimed composition must be enabled under 35 U.S.C. § 112. That is not the law. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) ("[T]he law makes clear that the specification need teach only one mode of making and using a claimed composition").

## IV. CENTOCOR'S OBVIOUSNESS DEFENSE FAILS AS A MATTER OF LAW

As with its written description and enablement defenses, Centocor's obviousness defense focuses on facts that are irrelevant to the obviousness inquiry. Centocor apparently contends that a claim to a composition of matter is rendered obvious because tools that could be used to make

the composition are in the prior art. Specifically, Centocor points to two technologies that it claims could have enabled one of ordinary skill in the art to arrive at the claimed invention: transgenic mouse technology and phage display technology. But, with respect to each technology, Centocor offers, at best, conclusory testimony from its expert that cannot be squared with the testimony of Centocor's own witnesses, and Centocor's deposition designations of Abbott scientists, who all testified that the technologies available to make human antibodies in 1999 were fraught with unpredictability. *See* Trial Transcript, Day 3 at 117:18-118:3 (Jill Giles-Komar Testimony: "Q. And ***when you start with a particular antigen, you don't know whether it's going to be predictable or not, do you? A. That's correct***. Q. And that was true in 1997, correct? A. That's true in 1997. Q. In 1998, correct? A. Correct. Q. In 1999, correct? A. Correct.") (emphasis added); *see also* Ex. 2009 (Sworn Video Deposition Testimony of John Elvin: "Q: Just a few follow-ups. At the start of the IL-12 project, ***you had no expectation of getting a clone like Joe 9 out of phage display***? A: No, at the start of that selection strategy, at the start of the selection strategy that led to Joe 9, I was using free p40 to try and trap things that were binding to p40 and get them away from binding to the dimer p70. ***Q. So you had no expectation that you were going to get a clone like Joe 9 from those experiments? A. It was a surprise, yes***. I was surprised because who would have predicted that you would get an antibody that actually bound p40 but was not inhibited by soluble p40. That was a surprise.") (emphasis added).

In addition, any claim that Abbott obtained the invention quickly or easily using phage display (which is contradicted by the facts) is irrelevant by statute. *See* 35 U.S.C. § 103 ("Patentability shall not be negatived by the manner in which the invention was made."). The mere fact that a technology like phage display could be made and used by persons of

extraordinary skill (such as the phage display experts at CAT) to obtain the claimed invention says nothing about whether the invention is obvious.

Because Centocor has not shown that a person of ordinary skill in 1999 could reasonably expect to obtain the claimed invention using either the technologies or starting materials available at that time, judgment as a matter of law should enter against Centocor's claim of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (explaining that an "obvious to try" defense requires proof that "there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp").

## V. CENTOCOR'S ANTICIPATION DEFENSE FAILS AS A MATTER OF LAW

In its apparent attempt to prove anticipation of Abbott's patents by Stelara, Centocor relies on an alleged reduction to practice of Stelara in 1997 or 1998. (Centocor has offered no evidence of prior conception.)

As an initial matter, Centocor's defense must fail because Centocor provided no evidence by any inventor of a date on which the inventor appreciated that the invention worked for its intended purpose. *See Yorkey v. Diab*, 601 F.3d 1279, 1286 (Fed. Cir. 2010) (explaining that to establish an actual reduction to practice, the inventor must "contemporaneously appreciate that the embodiment worked and that it met all the limitations of the interference count."); *see also id.* ("With the exception of very simple inventions … demonstration that the invention works for its intended purpose requires testing."). Accordingly, the Court should grant judgment as a matter of law rejecting Centocor's anticipation by prior invention defense.

In addition, in pretrial proceedings, Centocor has suggested that it believes that prior invention must be corroborated by the testimony of non-inventors. This is not the law. *See*

*Sandt Tech., Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1350-51 (Fed. Cir. 2001). ("Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated."). Moreover, Centocor's anticipation defense relied on the testimony of three scientists who participated in making Stelara (namely, John Ghrayeb, Kim Staquet and Jill Giles-Komar). Accordingly, if "non-inventor" testimony were required for corroboration, the testimony of Centocor's witnesses would not be sufficient to corroborate Centocor's prior invention story, and thus Centocor's anticipation defense would fail as a matter of law.

## VI. CONCLUSION

For the foregoing reasons, Abbott respectfully requests that the Court grant judgment as a matter of law that the asserted patent claims are not invalid.

September 18, 2012

Respectfully submitted,

*/s/ Robert J. Gunther, Jr.*

Robert J. Gunther, Jr. (admitted *pro hac vice*)
Jane M. Love (admitted *pro hac vice*)
Anne-Marie Yvon (admitted *pro hac vice*)
Violetta G. Watson (admitted *pro hac vice*)
Paula Estrada de Martin (admitted *pro hac vice*)
Barish Ozdamar (admitted *pro hac vice*)
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
New York, New York 10007
Tel: (212) 230-8800
Fax: (212) 230-8888

William F. Lee (BBO # 291960)
Anne M. McLaughlin (BBO # 666081)
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6000
Fax: (617) 526-5000

William G. McElwain (BBO # 332510)
Amy K. Wigmore (admitted *pro hac vice*)
Amanda L. Major (admitted *pro hac vice*)
Jacob S. Oyloe (admitted *pro hac vice*)
Rachel L. Weiner (admitted *pro hac vice*)
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Tel: (202) 663-6000
Fax: (202) 663-6363

William W. Kim (admitted *pro hac vice*)
Arthur W. Coviello (BBO # 670152)
WILMER CUTLER PICKERING HALE AND DORR LLP
905 Page Mill Road
Palo Alto, CA 94304
Tel: (650) 858-6000
Fax: (650) 858-6100

*Attorneys for Abbott GmbH & Co., KG, Abbott Bioresearch Center, Inc. and Abbott Biotechnology, Ltd.*

**CERTIFICATE OF SERVICE**

I certify that, on September 18, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Arthur W. Coviello